BioMimetic Therapeutics Announces No Changes Requested by Independent Data Monitoring Committee to Pivotal Trial Design for Augment™ Bone Graft; 268 of 396 Patients Enrolled to Date in U.S. Pivotal Trial

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(source: BioMimetics.com)

BioMimetic Therapeutics, Inc. (NASDAQ: BMTI) announced today results from the independent Data Monitoring Committee (DMC) that is overseeing the Company's ongoing U.S. pivotal trial evaluating Augment Bone Graft for the treatment of foot and ankle fusions. Based on the DMC's review of all available safety data from the first 254 patients and a futility analysis on data from the first 79 patients to have completed their six month follow up visit, the DMC has recommended that the Company's pivotal trial should proceed unchanged.

"Based on our careful review of all available safety data, as well as a futility assessment in this subset of patients, I am comfortable recommending that BioMimetic's U.S. pivotal trial proceed unmodified," stated the chair of the independent DMC.

"We are very pleased with the results of the DMC's safety and futility analyses, which are consistent with Augment technology's substantial history of safety and efficacy" said Dr. Samuel Lynch, president and CEO of BioMimetic Therapeutics. "We now eagerly look forward to completion of the ongoing pivotal trial." In light of the positive results already achieved in the U.S. pilot study and the Canadian clinical study, both of which assessed the use of Augment Bone Graft treatment in foot and ankle fusion applications, as well as the initial increase in sample size from 280 to 396 patients, the Company believes that the current sample size is likely sufficient to meet the study's endpoint of demonstrating non-inferiority of Augment as compared to autograft. Therefore, in advance of the meeting held by the DMC, and after consultation with members of the DMC, biostatisticians and regulatory advisors, BioMimetic directed the DMC not to consider potential changes to the study's sample size other than futility.

Previously Announced Clinical Data from 90 Patients in Foot and Ankle Fusion Indications

Previously reported clinical studies have demonstrated that Augment Bone Graft achieved fusion rates comparable to those expected using autograft, the current gold standard for bone grafting materials, but without the morbidity and extra operating room and anesthesia time required to harvest autograft.

In the 20 patient U.S. pilot study evaluating safety and efficacy of Augment Bone Graft in foot and ankle fusions, an assessment of CT scans of the fusion site by an independent reviewer blinded to the treatment found that at 12 weeks 69% of Augment Bone Graft and 50% of autograft patients had achieved greater than 50% osseous bridging.

In the 60 patient Canadian clinical study evaluating the safety and clinical utility of Augment Bone Graft for the treatment of foot and ankle fusions, the results demonstrated that 90% of the patients, which included a large percentage of high risk individuals, achieved a successful outcome based upon return to full weight-bearing (FWB) and lack of need for revision surgery at the nine month study end point. Radiographic fusion as measured by plane film X-ray was 88% at the 9 month end point. Since many of these fusion cases involved more than one joint in the foot and ankle, an analysis of clinical success for all fused

joints was also performed. These results indicated that 124 of a total of 130 joints treated achieved a successful clinical outcome, for an overall 95% rate.

The Company also recently announced results from its study investigating the use of Augment Injectable Bone Graft in patients being treated for foot and ankle fusions. A total of 10 patients were enrolled in this open-label study, seven of which were considered high risk for poor healing as a result of co-morbidities. The results of the study demonstrated that 100% of the patients achieved complete clinical success at six months after surgery. Additionally, analysis by CT scans demonstrated 90% fusion rates at three to four months post treatment.

To date, the Company has seen no serious adverse events (SAEs) related to the device in any of its trials.

Study Design

As announced previously, the U.S. pivotal study is designed as a randomized controlled non-inferiority trial comparing Augment Bone Graft to autograft, with the two treatments randomized 2:1, respectively. The primary study endpoint is a comparison between the two groups of the percent of patients fused as measured by CT scan at six months. The study will enroll up to 396 patients in the United States and Canada.

The trial design and sample size are comparable to previous trials utilizing bone growth factors for orthopedic applications in fusions. Medtronic's INFUSE® Bone Graft product for spinal fusions associated with treating degenerative disc disease was tested in a prospective, randomized, non-inferiority clinical trial involving 279 patients and 16 investigative sites. Since receiving FDA approval, hundreds of thousands of patients have been treated with INFUSE. Further, an additional ongoing clinical study utilizing OP-1, a growth factor developed by Stryker Corporation for a spinal fusion indication, analyzed plain film radiographic data in the initial trial. However, the trial has since been extended to include CT scans due to their higher sensitivity modality.

"We have implemented a high quality, well designed trial," continued Dr. Lynch. "The fact that our trial is utilizing CT scans and evaluating a much larger patient population than an already approved, successful biologic product only supports the strength in our study design and protocols. We set a high level of scientific rigor for our pivotal trial at its outset and are committed to its successful completion."

Enrollment Update

As of September 23, 2008, BioMimetic has enrolled 268 patients in its U.S. pivotal trial on Augment Bone. This compares to 220 patients enrolled as of the Company's last earnings conference call on August 8, 2008. There are currently 31 sites actively enrolling patients in the United States and Canada. The Company previously announced several initiatives expected to positively impact enrollment and has already begun to see the value in these new programs. Some of the initiatives that were implemented include the hiring of a team of clinical specialists to work directly with sites to identify and overcome enrollment obstacles, a physician to physician referral program and a challenge grant offered to the outreach and educational foundations of both the American Orthopedic Foot and Ankle Society (AOFAS) and the Canadian Orthopedic Foot and Ankle Society (COFAS). The Company also added new, high volume clinical sites to replace the sites that were enrolling more slowly.

With these initiatives in place and positively impacting enrollment, the Company reiterates its

previously announced enrollment timeline and expects enrollment completion around year-end 2008 or early in 2009.

About BioMimetic Therapeutics
BioMimetic Therapeutics, Inc. is developing and commercializing bio-active recombinant protein-device combination products for the healing of musculoskeletal injuries and disease, including orthopedic, spine and sports injury applications. BioMimetic received marketing approval from the FDA in 2005 for its first product, GEM 21S, for regeneration of bone and periodontal tissue loss resulting from periodontal disease. Currently, the Company has clinical trials ongoing with its product candidates Augment™ Bone Graft (formerly GEM OS1) and Augment™ Injectable Bone Graft (formerly GEM OS2) in multiple orthopedic bone healing indications including the treatment of foot and ankle fusions and the stimulation of healing of fractures of the wrist. The Company's lead product candidates all combine recombinant human platelet derived growth factor (rhPDGF-BB) with tissue specific scaffolds to actively stimulate tissue healing and regeneration.

GEM 21S® is a registered trademark of Luitpold Pharmaceuticals, Inc., who owns and markets that product through its Osteohealth Company division for use in periodontal and cranio-maxillofacial applications.

For further information, visit www.biomimetics.com or contact Kearstin Patterson, associate director of corporate communications, at 615-236-4419.

Forward-looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the current intent and expectations of the management of BioMimetic. These statements are not guarantees of future performance and involve risks and uncertainties that are difficult to predict. There are many important factors that could cause actual results to differ materially from those indicated in the forward-looking statements. BioMimetic's actual results and the timing and outcome of events may differ materially from those expressed in or implied by the forward-looking statements because of risks associated with the marketing of BioMimetic's product and product candidates, unproven preclinical and clinical development activities, regulatory oversight, and other risks detailed in BioMimetic's filings with the Securities and Exchange Commission. Except as required by law, BioMimetic undertakes no responsibility for updating the information contained in this press release beyond the published date, whether as a result of new information, future events or otherwise, or for changes made to this document by wire services or Internet services.